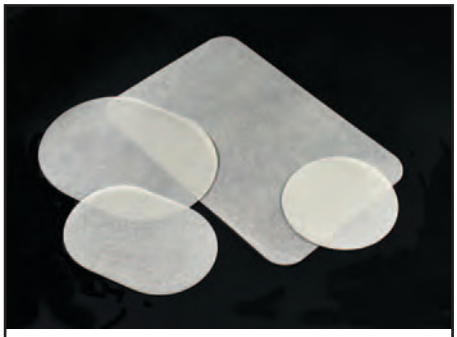
MATERIAL INNOVATIONS

Volume 1, Issue 3

Building on the Strengths of Previous Technologies: Offering a New Solution for Hernia Repair

A next-generation biomaterial for ventral hernia repair builds upon the relative advantages of both synthetic and biologic categories from which previous devices have emerged. The new biomaterial developed by W. L. Gore & Associates, Inc, GORE® SYNECOR Biomaterial, offers the logical next step and creates an optimal category, building on the strengths from previous technologies to offer a new solution for surgeons. "It became obvious to me that the concepts that have guided development of previous products need to be melded together. The latest Gore biomaterial does this, and I think this advances us down the path we have been heading," said Karl A. LeBlanc, MD, FACS, a member of the Surgeons Group of Baton Rouge, in Baton Rouge, Louisiana. Dr. LeBlanc has extensive experience in ventral repair and was among those who urged Gore scientists to pursue a device with the characteristics now reflected in the GORE® SYNECOR Biomaterial.



GORE® SYNECOR Biomaterial

"I was fortunate to be involved in the first case using GORE® SYNECOR Biomaterial, and I think this biomaterial has features that will reduce hernia recurrences," Dr. LeBlanc reported. "It will be easiest to show the advantage of this device in more challenging patients, such as those with previous recurrences, and those same features that will yield a permanent repair in these patients will be meaningful in reducing risk for complications in less challenging repairs."

With GORE® SYNECOR Biomaterial, Gore answers the need for providing enduring strength and patient comfort, while minimizing unfavorable foreign-body reactions and other threats to device survival, according to Dr. LeBlanc. Specifically, the hybrid device joins the absorbable material employed in the clinically proven GORE® BIO-A® Tissue Reinforcement with conformable polytetrafluoroethylene, an inert material that will not degrade.

"By creating a hybrid product, there is no compromise in strength even as the biodegradable GORE® BIO-A® Web generates appropriate tissue integration," Dr. LeBlanc explained.

see **SOLUTION**, page 4

An Optimal Balance of Innovations: The Science of GORE® SYNECOR Biomaterial

GORE® SYNECOR Biomaterial is the first intraperitoneal ventral hernia repair bridging device to effectively address the key challenges in durable repair for high-risk patients, according to scientists involved in its development. By incorporating layers that include a porous GORE® BIO-A® Web tissue-building scaffold, a conformable monofilament polytetrafluoroethylene (PTFE) fiber knit, and a nonporous polyglycolic acid and trimethylene carbonate (PGA/TMC) film, the device ties together several mutually reinforcing strategies.

"We have leveraged several of our proprietary technologies to create a device suitable for hernia repairs in patients for whom the risk for post-op complications is substantial and for whom previous products, including biologics, have not provided consistent rates of success," explained Natalie Crawford, DVM, MS, research pathologist at W. L. Gore & Associates, Inc.

In ventral hernia repair, much has been learned about bridging materials by evaluating the strengths and weaknesses of biologic and synthetic mesh reinforcements. As an

see **BALANCE**, page 3

Upcoming Course Schedule

SYMPOSIA AND TRAINING

ADVANCED HERNIA IN GENERAL SURGERY

February 2017
Charlotte, NC

Description: This symposium will provide surgeons the opportunity to further refine their knowledge of advanced surgical techniques and management of complex hernias. It will combine presentations, a panel discussion, and case reviews.

Participants: General, Trauma, and Plastic Surgeons

Learning Outcomes:

- Expand knowledge and refine techniques associated with component separation and abdominal wall hernia repair.
- Become familiar with abdominal wall reconstruction, including component separation.
- Be knowledgeable about biomaterial choices and the similarities and differences between bioabsorbable and biologic mesh.
- Understand patient risk factors that may influence choice of repair or biomaterial.
- Discuss complex hernia cases and management of complications.

OPTIMIZING OUTCOMES IN HERNIA AND BARIATRIC SURGERY

February 2017
Miami, FL

Description: This educational event will focus on surgical techniques for complex hernia repair and bariatric procedures through didactic instruction and/or video and case discussion.

Participants: General and Bariatric Surgeons

Learning Outcomes:

- Become knowledgeable about biomaterial choices and the similarities and differences between biosynthetics and biologics.
- Understand patient risk factors that may influence choice of repair or biomaterial.
- Understand the role of robotics in hernia and bariatric surgery.
- Expand knowledge and refine techniques associated with component separation and abdominal wall hernia repair.
- Discuss complex hernia cases and management of complications.
- Understand the indications for various bariatric revisional surgery procedures.
- Demonstrate the safe and effective use of staple line reinforcement in various procedures.
- Develop preoperative and intraoperative strategies and techniques to prevent complications and treatment failures of bariatric surgery.
- Understand how to manage complications arising from various bariatric procedures, including revisional surgery.
- Understand the critical components for handling hiatal hernia at the time of surgery.
- Discuss the changing landscape of health care economics in bariatric surgery—cost of complications and economic outcomes.

BALANCE

continued from page 1

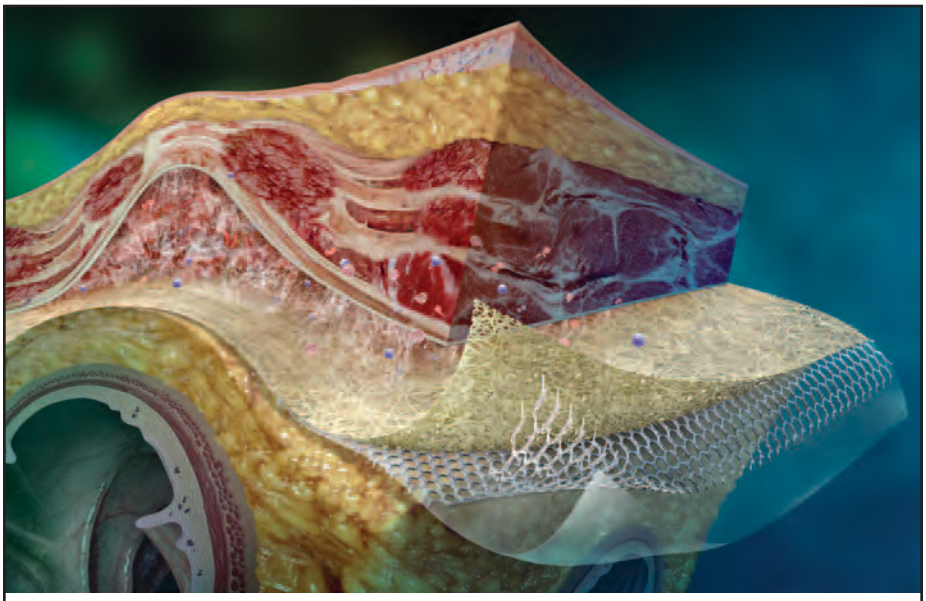
alternative to biologic meshes harvested from cadavers or animals, GORE® SYNECOR Biomaterial combines an inert permanent layer with the biosynthetic and completely bioabsorbable GORE® BIO-A® Web to support rapid infiltration of cells critical to ingrowth of quality, well-vascularized tissue.

"Biologics largely lack porosity so that cell penetration is relatively poor, especially in the early phase of wound healing," explained Ji Zhang, PhD, research scientist at W. L. Gore & Associates. Furthermore, "the lack of cell penetration concentrates the inflammatory process to the surface of the biologic, which in turn leads to slow and inconsistent degradation."

In contrast, the porous GORE® BIO-A® Web layer of the GORE® SYNECOR Biomaterial is degraded primarily through hydrolysis. Over the course of six months, the scaffold is gradually absorbed as vascularized soft tissue replaces the GORE® BIO-A® Web, according to Dr. Zhang.

The PTFE knit, which is integrated between the GORE® BIO-A® Web and the nonporous PGA/TMC film, is inert and permanent. It also has specific features that enable strength while minimizing bacterial colonization. The PTFE knit has a pore size ranging between 1.0 and 3.0 mm, which facilitates tissue integration. The combination of the PGA/TMC web and the PTFE knit contributes to the favorable handling characteristics of GORE® SYNECOR Biomaterial without sacrificing strength.

"Using state-of-the-art understanding of biomaterials and in vitro and in vivo testing, the GORE® SYNECOR Biomaterial device was engineered to generate healthy well-organized and well-vascularized tissue while maintaining strength," Dr. Crawford said.



GORE® SYNECOR Biomaterial includes a porous GORE® BIO-A® Web tissue-building scaffold, a conformable monofilament PTFE fiber knit, and a nonporous PGA/TMC film.

PTFE, polytetrafluoroethylene; **PGA,** polyglycolic acid; **TMC,** trimethylene carbonate

Many variables important to optimal bridging material intersect. Tissue ingrowth and vascularity, for example, correlate with the quality of wound healing and repair. Evidence suggests that the monofilament knit employed in GORE® SYNECOR Biomaterial is also associated with a relatively low risk for bacterial adherence, according to Dr. Crawford.

"The PTFE knit in GORE® SYNECOR Biomaterial is engineered with a dense, high-strength fiber reducing the risk of harboring bacteria," Dr. Crawford explained.

In creating GORE® SYNECOR Biomaterial, the goal was to improve further on past designs and continue to advance clinically relevant metrics in order to test innovations. For strength, some device manufacturers have published data on tensile strength, but the researchers at Gore have focused on burst strength for relevance to clinical performance.

"Burst strength is a more realistic measure for a bridging mesh in the abdominal cavity, because it more closely simulates the application setting. In the abdominal cavity, the biomaterial is fixated around its edges and subjected to a biaxial load," Dr. Zhang said. According to Dr. Zhang, this is not only relevant to patients with a high body mass index but also reassuring for other situations that may result in abdominal strain, such as physical exercise.

Devices must balance benefits with risks. Strength in synthetic materials is an attribute if it does not induce a chronic inflammatory response, cause discomfort to the patient, or create a medium for bacterial growth. Degradable mesh is an advance only if tissue ingrowth is well organized and vascularized before degradation is complete. "The work behind GORE® SYNECOR Biomaterial focused on identifying gaps in permanent mesh device design, as well as looking at clinically relevant measures that would address those gaps," Dr. Zhang reported.

SOLUTION

continued from page 1

The hybrid material also has favorable handling characteristics, according to Dr. LeBlanc. Although he conceded that the optimal degree of stiffness is case-specific, GORE® SYNECOR Biomaterial strikes a balance. "It is well suited to robotic procedures, which I have been using with increasing frequency, as well as open and laparoscopic procedures. In any specific case, I may wish for more or less stiffness, but overall I can say that GORE® SYNECOR Biomaterial has the relative degree of stiffness that I have been looking for," Dr. LeBlanc said.

There are many patients for whom GORE® SYNECOR Biomaterial is particularly appropriate, such as those at increased risk for recurrence due to a previous repair failure, with a high body mass index, or with poor collagen metabolism, according to Dr. LeBlanc. He suggested that GORE® SYNECOR Biomaterial might offer a single-stage repair in a patient who might otherwise require a two-stage procedure. Therefore, the cost advantages of this device may extend to a much larger population if a low rate of recurrence can be made even lower.

"Every recurrence is costly, and not just in the sense of the cost of redoing the procedure," Dr. LeBlanc explained. While avoiding complications or second procedures has great value to the patient, quality initiatives being widely implemented also raise the value and relevance of these issues to physicians and the institutions where they practice. "Increasingly, reimbursement will be to some extent based on outcomes, and this is increasing the pressure to reduce complications. This need will shift attention from the cost of acquiring a device like GORE® SYNECOR Biomaterial to its relative value for improving outcomes even among routine cases," Dr. LeBlanc suggested.

Surgeons using GORE® SYNECOR Biomaterial have been invited to participate in a Clinical Quality Improvement (CQI) project, rapidly capturing outcome data relevant to the mesh as well as to other variables in ventral hernia repair. "The CQI project is important because it will help us identify steps associated with better outcomes. This quality improvement program is not just tracking major events, like infection or device failure, but a broad array of real-world interacting variables that may guide us to improvements. Gore is one of the few companies taking this type of initiative to track clinical experience, and it is going to be helpful," Dr. LeBlanc observed.

The data points in this ongoing CQI initiative are just beginning to accrue, but Dr. LeBlanc is looking forward to hard data. "I am very optimistic," Dr. LeBlanc said. He advised surgeons to understand which cases are likely to most benefit from the features of GORE® SYNECOR Biomaterial, but he considers this biomaterial a significant step forward in ventral hernia repair.

Value Versus Cost: Identifying Key Priorities in Selecting Biomaterials

The cost of care is calculated from the sum of resources required to achieve a treatment goal. For biomaterials purchased to improve outcomes in intraperitoneal hernia repair, how outcomes define value is fundamental to cost-of-care calculations. "In ventral hernia repair, the era when hospitals and other centers were primarily focused on case volume has passed. We are seeing reimbursement increasingly based on episodes of care to capture the true costs of achieving a specific outcome," said Karen Root, Strategic Marketing, W. L. Gore & Associates, Inc.

For any given case, "complications following placement of a tissue reinforcement device, such as infection, can increase the cost of an episode of care by several-fold. Even a small increased risk for complications is meaningful, and not just in terms of direct cost. It is important to recognize the value of keeping complication rates low for outcomes relevant to patient satisfaction and peer institution comparisons," Ms. Root added.

Gore is tracking value specifically in the real-world use of GORE® SYNECOR Biomaterial through a Clinical Quality Improvement (CQI) project, according to Lori Norton, PhD, a product specialist at W. L. Gore & Associates. With data captured on a broad array of metrics in the absence of exclusion or inclusion criteria, the CQI will generate insights on how to better optimize care.

"The CQI is capturing information relevant to the surgery and perioperative care, not just to the performance of GORE® SYNECOR Biomaterial. We are anticipating deep-dive analytics from the CQI database to generate new information on broad aspects of ventral hernia repair," Dr. Norton explained.

GORE® SYNECOR Biomaterial, designed for high-risk hernia repairs requiring high strength, such as those patients with a high body mass index, is intended to deliver consistent outcomes across patient characteristics.

The acquisition cost of GORE® SYNECOR Biomaterial can be less than half of some biologic meshes. However, acquisition costs are but one part of a value calculation that includes the likelihood of a satisfactory and durable outcome. Due to variability in risk for infections, device failure, or other complications, these are patient-specific. "GORE® SYNECOR Biomaterial is available at very competitive pricing, but it is essential for surgeons and institutions to look beyond up-front costs for how the quality of the outcomes affects patients, surgeons, and the institutions where the ventral hernia repair is performed," Ms. Root maintained.

AV0588-EN1